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Docket # 99-255

April 16, 1999

The Honorable William E. Kennard
Chairman
Federal Communications Commission
445 12th Street, S.W.
Room 8-B201
Washington, D.C. 20554

Dear Chairman Kennard:

Nearly 14 months ago, the initiation of Digital Television Service in Dallas created unanticipated interference with wireless biomedical telemetry devices operating at the Baylor University Medical Center in Dallas, Texas. In response to that incident and a growing number of problems of interference to wireless medical telemetry devices from land mobile systems, the American Hospital Association (AHA) -- working with the staffs of the Federal Communications Commission (FCC) and the Food and Drug Administration -- created a Task Force to study this problem and determine solutions. On January 21, 1999, I submitted to you the preliminary reports of a number of work groups that were created with representatives of health care facilities, manufacturers, and health care practitioners, and with liaisons from trade associations representing users in the licensed services and the FCC.

I am pleased to submit to you the AHA Task Force's Report, a consolidated and comprehensive consensus recommendation of the Task Force, which addresses the potential critical safety risks to patients from interference with wireless medical telemetry. The Task Force recommends the allocation of dedicated spectrum that can reasonably satisfy the nation's current and anticipated requirements for wireless biomedical telemetering capabilities in a relatively interference-free environment. The report also contains proposals for a process that should ensure that the dedicated spectrum is utilized efficiently and without creating interference between or among authorized users of the designated bands.

In light of the substantial efforts already undertaken by the Commission's staff in conjunction with the Task Force's efforts, we are hopeful that the submitted recommendations can form the basis for the FCC to issue a Notice of Proposed Rulemaking to initiate the proposed allocation.

AHA 100 YEARS

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We believe that there is broad-based support in the health care field, and among the broadcasting and land mobile communities, for resolving the growing interference problem with such an allocation. We urge the Commission to act quickly on these recommendations in order to implement a new, interference-free allocation of spectrum for a Wireless Medical Telemetry service, so that the nation's health care providers can continue to efficiently provide this critical element of patient care.

We look forward to working with you and your staff to reach a favorable conclusion on this patient safety issue.

Sincerely,

Rick Pollack

Rick Pollack
Executive Vice President

Enclosure

REPORT OF THE
AMERICAN HOSPITAL ASSOCIATION
TASK FORCE ON MEDICAL TELEMETRY

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REPORT OF THE AMERICAN HOSPITAL ASSOCIATION TASK FORCE ON MEDICAL TELEMETRY

The American Hospital Association ("AHA") created a Task Force on Medical Telemetry in 1998, in order to study, and make recommendations, concerning the growing problem of interference to biomedical telemetry devices from licensed radio services. Various workgroups were created to study specific elements of the problem, including future spectrum requirements for the industry, possible frequency bands in which to operate with less interference, and a regulatory regime by which this critical element of the health care industry could meet patient needs in a less congested radiofrequency ("RF") spectrum environment. It is with great pleasure that the AHA presents the Commission with a consolidated recommendation[1] for the allocation of dedicated spectrum that can reasonably satisfy the nation's current and anticipated requirements for wireless biomedical telemetering capabilities in a relatively interference-free environment. We believe that this recommendation can, and should, expeditiously form the basis for a *Notice of Proposed Rulemaking* from which the Commission can implement a new, interference-free allocation of spectrum for a Wireless Medical Telemetry service.

INTRODUCTION

Wireless biomedical telemetry devices are used in hospitals to transmit waveforms and other physiological data from patient measurement devices to a nearby receiver's antenna. One of the main purposes of patient monitoring is early detection of life-threatening physiologic developments so that appropriate intervention can be rendered in a timely manner in support of recovery. Typical devices may monitor ECG, oxygen saturation, blood pressure or respiration. The use of these devices offers patients mobility earlier in their recovery, as well as improved comfort while still being monitored for adverse symptoms. Early mobility is particularly important for the recovery of cardiac and certain other patients, but could be dangerous in the absence of telemetry monitoring. In addition, such devices allow more patients to be monitored by each health care worker, thus decreasing health care costs.

The profile of telemetry patient monitoring is expanding. While recovering cardiac patients continue to represent the largest segment of patients being monitored by wireless telemetry, more acute patients are also being monitored, as are the supplemental devices, *e.g.*, ventilators, infusion pumps, *etc.*, that support them. Indeed, reference to "wireless medical telemetry" must now include all measurement and recording of physiological parameters and

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[1] This consolidated recommendation presents the efforts of four different workgroups; the reports of these workgroups were submitted to Chairman Kennard, by letter from Rick Pollack, Executive Vice President, Government and Public Affairs, of the American Hospital Association, dated January 21, 1999. Each of whose reports, containing substantially more detailed analysis, is also separately attached in Appendix II.

other patient-related information via radiated bi-directional and uni-directional electromagnetic signals in order to accommodate future developments within the industry. In addition, consideration must be given to the use of such devices in a broad array of environments constituting health care facilities, including not merely hospitals, but also in other establishments that offer services, facilities, and beds for use beyond 24 hours in rendering medical treatment, and in institutions and organizations regularly engaged in providing medical services through clinics, public health facilities, and similar establishments, including governmental entities and agencies for their own medical activities.

The FCC currently accommodates the use of biomedical telemetry devices on an unlicensed basis in the 174-216 MHz (VHF TV channels 7-13) and 470-668 MHz (TV Channels 14-46) bands under Part 15 of its rules and at higher power levels in the 450-470 MHz band on a licensed basis under Part 90.[2] Part 15 permits operation of biomedical telemetry devices with field strengths of 200 mV/m, measured at three meters,[3] while hospitals or health care institutions that already hold Part 90 licenses are permitted to operate medical radio telemetry devices in the 450-470 MHz band without additional specific authorization with output powers up to 20 mW (330 mV/m at three meters).[4] Operation of biomedical telemetry devices in these bands is generally subject to the condition that no interference may be caused to any other user, and all interference from any other use of the band must be tolerated.[5]

The spectrum needs of the medical community for biomedical telemetry operations were considered as recently as 1997, when the Commission concluded a study of the industry's growth in ET Docket No. 95-177. As a result of the information submitted in that proceeding, the FCC modified its Part 15 rules (a) to expand the frequency bands in which such devices could operate

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2 *See* 47 C.F.R. §§ 90.20(d)(27), 90.35(c)(30), 90.238(e), and 90.267.

3 *See* 47 C.F.R. § 15.242.

4 *See* 47 C.F.R.§ 90.267(a)(5). Moreover, under Section 90.238(e), health care facilities may be licensed to operate individual medical telemetry devices at output powers up to 2 watts.

5 *See, e.g.*, 47 C.F.R. § 15.5. Under the Refarming Order [see n. 13, infra], it is possible that some low-powered medical telemetry devices would be allowed co-primary status, but the number of "low powered" channels has not yet been determined, and low-power devices will not be able to effectively co-exist on a co-primary basis with higher powered devices operating under the Refarming Order.

and (b) to allow for increased power by such devices within those new bands.[6] At the time, the Commission recognized the possibility that biomedical telemetry devices might create interference to the use of the television bands by recently-authorized advanced digital television ("DTV") and low power television services ("LPTV"). However, the agency believed that the number of channels available for use by wireless medical telemetry devices and the technical parameters adopted for such devices in that rulemaking, would be adequate to protect such licensed services from interference. As the Commission then concluded, "these changes support spectrum efficiency by facilitating the sharing of scarce radio spectrum and facilitating use of radio spectrum to provide cost-efficient and needed medical technologies to health care communities."[7]

At the time these new allocations were considered under Part 15, a number of commenters asked the Commission also to consider allocating dedicated spectrum for the use of biomedical telemetry devices, especially in light of the then forthcoming introduction of DTV in the VHF and UHF bands. However, the Commission deferred consideration of a dedicated spectrum allocation,[8] finding that the record before it was not sufficiently complete to determine which, if any, additional channels should be employed. Nonetheless, the Commission did recognize that "sufficient TV channels may not be available for biomedical use in all major cities [and] [w]ith regard to the forthcoming introduction of DTV, for some period of time coordination may prove more challenging for biomedical telemetry device users."[9]

In the eighteen months that have followed the adoption of those new rules, the use of wireless biomedical telemetry in health care has continued to expand, even as the profile of the telemetry patient has changed to include more categories of acute patients and associated supplemental devices that support them. Contrary to the Commission's hopes, the introduction of DTV in the major markets and the anticipated increase in the number of applicants for LPTV stations has already created a real potential for interference to the existing and future uses of the allocated television bands for wireless medical telemetry.[10] At the same time, the Commission's

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6 *Amendment of Part 15 of the Commission's Rules to Permit Operation of Biomedical Telemetry Devices on VHF TV Channels 7-13 and UHF TV Channels 14-46, Report and Order*, 12 FCC Rcd 17828 (1997) (the "1997 R&O").

7 1997 R&O at 17828.

8 *Id.* at 17832.

9 *Id.*

10 *See, e.g.*, Office of Engineering and Technology Fact Sheet, "Sharing of Analog and

(continued...)

decisions on "refarming" the land mobile bands has similarly introduced a greater threat of interference to the use of the available UHF bands for wireless medical telemetry. The decisions in that proceeding authorize higher powered devices operating on the offset frequencies that have been used for lower powered medical telemetry; as a result, the available spectrum is shrinking as the need for wireless medical telemetry is increasing.

In light of these developments, the Task Force was created to determine a realistic projection of the uses of wireless medical telemetry for the coming decades, and to study and recommend means of satisfying those requirements. After much debate, the Task Force has determined that a real and present need exists for deployment of interference-free wireless medical telemetry. The Task Force further concluded that such need requires access to new spectrum on a primary basis to meet the immediate and foreseeable needs of the health care industry and to protect future advanced DTV and Private Land Mobile Radio ("PLMR") Services from creating, or being the object of, potential interference.

DISCUSSION

I. There is a clear need for additional, dedicated spectrum to satisfy the reasonably foreseeable needs of the health care industry for reliable, efficient, wireless medical telemetering capabilities.

The biomedical telemetry industry has developed devices for low-power, unlicensed, secondary or shared (which we will refer to as "secondary" as well) uses of the spectrum under Parts 90 and 15. However, the greater need for wireless medical telemetry by health care providers and the increased use of these bands for non-medical purposes makes this status no longer a feasible, long-term alternative. Ironically, in the 1997 debate over whether to expand the frequencies that could be available for biomedical telemetry under Part 15, both the broadcast and the health care industries agreed that biomedical telemetering devices should not be subject to a substantive risk of interference from licensed devices any more than they should be in a position to create interference to licensed devices.[11]

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[10] (...continued)
Digital Television Spectrum by Medical Telemetry Devices," March, 1998; *see also* "Joint Statement of the Federal Communications Commission and the Food and Drug Administration Regarding Avoidance of Interference Between Digital Television and Medical Telemetry Devices," March 25, 1998.

[11] The Commission noted, for example, the comments of the Society of Broadcast Engineers that "potentially life-critical biomedical telemetry has no place as a 'bottom-of-the-food-chain" Part 15 device, while it noted the similar comments of the FDA's Center

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As secondary users of the frequencies on which they operate under Parts 90 and 15 of the Commission's rules, medical facilities must proactively manage the patient risks associated with the potential for interference from other primary users, by avoiding utilization of any frequencies known to be occupied by such users in their geographic area.[12] Furthermore, hospital personnel also need to react to transient interference, often from unknown sources, which is also expected to increase as usage by other primary licensees expands. The Task Force determined that this transient interference currently may be encountered several times per week (6-12 times depending on the reporting institution), potentially affecting the well being of a significant number of patients.

The Commission hoped that its decision to expand the available spectrum on which these Part 15 devices could operate would provide sufficient leeway from the primary licensees. Unfortunately, the advent of DTV services in the VHF spectrum (174-216 MHz) has resulted in increased potential for interference to biomedical telemetering devices in this spectrum. An incident of interference occurred at the Baylor University Medical Center in Dallas, Texas upon the initiation of one of the nation's first DTV stations; as noted above, the Commission has already issued public advisories urging broadcasters and health care facilities to work even more closely together to avoid additional incidents. In several cities where the VHF bands are already heavily utilized for analog television signals, the availability of any channels in this band is questionable once all of the broadcast stations introduce DTV on the few vacant channels remaining. Moreover, the upper UHF band (470-668 MHz) is still subject to interference from broadcast and low power television service use, which could increase significantly over time. There are virtually no biomedical telemetry products currently available on the market which utilize that portion of the spectrum, and the market for such products is likely to be limited in light of this potential interference risk. Simply stated, the current allocation of frequencies available under Part 15 will not satisfy the need for biomedical telemetry over the near, medium

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[11] (...continued)
for Devices and Radiological Health, which expressed concern about "the potential for injury to patients that might occur if there is interference between the medical device and the primary licensees." 1997 R&O at 17830, 17831.

[12] As the FCC has recognized, television broadcasters have been asked to notify health care facilities in their broadcast region of their intent to begin use of a previously unoccupied television channel for their DTV expansion. However, these notifications are not necessarily addressed to the hospital personnel who understand and can react appropriately, so that the interference often is identified only after the problem is created. Moreover, as the Commission has noted, in major markets where the television bands are already heavily utilized, the older biomedical telemetry devices may not have enough tuning range to move to the rare frequencies that remain unoccupied as all television stations begin their introduction of DTV on previously unauthorized channels.

or long terms, notwithstanding the FCC's decision to make new UHF bands available to the biomedical telemetry industry on a secondary use basis.

The situation in the 450-470 MHz band available under Part 90 is no less problematic. In the Commission's 1995 Refarming Order,[13] frequencies offset 12.5 kHz from the regularly assignable frequencies ("offset channels") that are heavily used for medical telemetry were made available for high power operations on a primary basis. The Commission left to the industry the task of developing a consensus plan for dedicating channels for low-power use in order to address the need for biomedical telemetry and other low-power services in this band, in conjunction with the formulation of a consolidation plan under the "Refarming" approach. However, as the Commission recognized in the Second Report in the same proceeding,[14] coordinators have been reluctant to designate any channels specifically for low power use due to the uncertainty surrounding consolidation of the PLMR Services; the effort to reach a consensus plan with users has therefore failed, reflecting in large measure the incompatibility of co-channel high powered mobiles and low-powered medical telemetry operations.

To protect existing low-powered uses of these channels, and until such new designations are completed, the Commission has frozen applications for higher powered stations on these offset channels.[15] Were that freeze on licensing co-channel, higher powered operation to be lifted without designating new, low-powered only channels,[16] and providing a transition plan, existing

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13 Replacement of Part 90 by Part 88 to Revise the Private Land Mobile Radio Services (Report and Order and Further Notice of Proposed Rule Making), 10 FCC Rcd 10076 (1995).

14 Replacement of Part 90 by Part 88 to Revise the Private Land Mobile Radio Services (Second Report and Order), 12 FCC Rcd 14307, 62 FR 18833 (1997).

15 *See* Public Notice, "Freeze on the Filing of High Power Applications for 12.5 kHz Offset Channels in the 450-470 MHz Band" (PR Docket 92-235, FCC 95-255), DA 95-1771, (released Aug. 11, 1995).

16 In the Second Report, the Commission delegated to the frequency coordinators the authority to designate low power frequencies, and to add or subtract from the designated list as may be warranted by local requirements. The agency expected low power operation on the designated channels to be protected through coordination and the Commission's licensing process. However, the frequency coordinators for the PLMR Service channels have not been able to develop a consensus on such a plan, largely because of the extreme difficulty of developing a coordination procedure that can reasonably protect lower powered operations such as biomedical telemetry from

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biomedical telemetering devices could not continue to operate in these bands because of disabling interference from the new higher powered users.[17] Indeed, even with the freeze, operation of biomedical telemetry devices pursuant to Part 90 is becoming more difficult, as adjacent-channel interference from licensed mobile operations continues to make some of the "frozen" offset channels unusable in certain locations. Moreover, increased congestion from low powered biomedical telemetry and other lower powered uses in the band is making it difficult for health care administrators to find any other frequencies to which to switch their operations when disabling interference makes a currently used channel unusable, or even to add more telemetry units when needed to provide care to patients.

The problems associated with a shrinking pool of quiet channels on which to operate in a relatively interference-free environment is exacerbated by the significant growth in the use of biomedical telemetry as a staple element in the provision of health care in the future. According to surveys taken of hospitals by the Task Force, many hospitals already have in excess of 300 patient-connected transmitting devices in use at one time. Those surveys also show that within 10 years, medium to large hospitals will use an *average* of 1,000 patient-connected transmitting devices. These devices will serve more types of acute patients and will monitor additional vital signs measurements. In sum, there is, in the Task Force's view, a clear and present need to develop a new approach for meeting the nation's need for wireless biomedical telemetry services. In this case, the need can best be satisfied by identifying specific frequency bands in which biomedical telemetry devices will have primary status.

Allocating frequencies for use by low powered devices and granting such devices regulatory parity with other higher powered licensed transmitters is no longer a novel idea within the Commission's spectrum allocation tools. This approach has been utilized in allocating spectrum for use on a primary basis for the Unlicensed Personal Communications Service,[18] to which specific frequencies were allocated for use under Part 15, Subpart D; it has also been used more recently in authorizing the use of spectrum under Part 15, Subpart E for the fixed,

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16 (...continued)
interference from higher powered mobile operations within the same geographic area. As discussed in Section V below, the Task Force does not believe that such coordination will be effective.

17 This concern has been confirmed through testing conducted by the Commission's Technical Research Branch in Columbia Maryland, which demonstrated that low powered biomedical telemetry devices could not co-exist with higher powered mobile devices operating on the same or adjacent channels.

18 Amendment of the Commission's Rules to Establish New Personal Communications Services, 8 FCC Rcd 7700 (1993).

point-to-point Unlicensed National Information Infrastructure ("U-NII") devices in the 5.725-5.825 GHz band.[19] In promoting the expansion of the 902-928 MHz bands for Location and Monitoring Services, the Commission has also recently created "safe harbor" technical criteria in which Part 15 unlicensed devices are able to operate with a presumption that they are not causing interference to any licensed services operating in the band.[20] A similar approach has also been utilized in creating licensed services: the Family Radio Service, for example, was created under Part 25, and through technical and operating rules, has been licensed to individuals "by rule"[21]; the Commission has also taken the same approach recently when it proposed the creation of a new Medical Implant Communications Service.[22]

In sum, as demonstrated in the Task Force Report, the public safety, health and welfare clearly justify the initiation of proceedings by the Commission to find adequate spectrum for use on a primary basis by wireless biomedical telemetry devices, to which such devices can readily migrate in order to operate without the threat of interference from other licensed and unlicensed devices.

II. The new allocation must have adequate bandwidth to accommodate existing and reasonably foreseeable demands for the use of wireless biomedical telemetering devices in the nation's health care system.

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19 Amendment of the Commission's Rules to Provide for Operation of Unlicensed NII Devices in the 5 GHz Frequency Range, 12 FCC Rcd 1576 (1997). The Commission did not believe that any public interest considerations warranted unique protection for U-NII devices beyond that created by the technical characteristics available to the bands' users, which are designed to avoid virtually all interference. However, the Task Force demonstrates below that health and public safety concerns will warrant a higher level of protection for wireless biomedical telemetry devices operating in any newly allocated bands, more akin to the primary allocation approach taken with Unlicensed PCS spectrum.

20 *See,.e.g., Amendment of Part 90 of the Commission's Rules to Adopt Regulations for Automatic Vehicle Monitoring Systems, Report and Order*, PR Docket No. 93-61, 10 FCC Rcd 4695 (1995).

21 Amendment of Part 95 of the Commission's Rules to Establish a Very Short Distance Two-way Voice Radio Service, 11 FCC Rcd 12977, 61 FR 28768 (1996).

22 Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, WT Docket No. 99-66, RM No. 9157, FCC 99-23 (released February 24, 1999).

It is clear to the Task Force that the demand for wireless biomedical telemetering is growing; therefore, any allocation of spectrum for such uses must therefore provide sufficient bandwidth so that any single health care facility's needs can be satisfied without creating internal or external interference to and among patients. As the Task Force found, there are a number of causes for this concern, including:

- Patient acuity is rising, *e.g.*, the typical hospitalized patient entering the hospital is sicker. This means that patients who in the past were housed in an intensive care unit are now, and in the future will in greater numbers be, housed on general nursing units where they still require the monitoring and treatment capabilities that were previously deliverable only in the intensive care setting. Moreover, patient outcomes are optimized by moving them from the intensive care unit to a general nursing unit as quickly as possible. All of these factors contribute to the increase in the number of telemetering units in use in any given facility.

- As a cost containment and quality improvement effort, hospitals desire to house patients in a specialty ward that is most capable of addressing that patient's acute health care needs; as a result, there is an emerging population of patients that require physiologic monitoring outside of the traditional hard-wired monitoring wards. There is also a growing need to include data acquisition from stand-alone equipment, monitoring devices, and therapeutic devices via telemetry.

- As consolidation of health care providers continues to escalate, the need for wireless telemetry will become more important as patient monitoring expands outside of the campus of the monitoring hospital to, for example, community based hospitals, ambulatory surgery centers, long-term facilities, and even home health care.

In light of all of these factors, the Task Force undertook a study to determine the industry's likely reasonable bandwidth requirements. This study included a survey of geographically dispersed hospital administrators, biomedical engineering directors, principal clinicians responsible for medical telemetry, and clinical professional organizations.[23] Based on the results of this survey, a model was developed based on the number of concurrently operating telemetry transmitters, and a 0.8 bit per second per Hertz spectral efficiency metric currently recommended by section 90.203 (which is better utilization than medical telemetry technology currently affords).

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[23] These professional groups included the American Association of Critical Care Nurses, the American College of Cardiology, the Society of Critical Care Medicine, the American Medical Association, the American Association of Respiratory Care, the American Academy of Neurology, and the American Association of Cardiovascular & Pulmonary Rehab.

With this study in hand, the Task Force now estimates that based on the number of wireless telemetry units that may currently be simultaneously operating within a health care facility or campus, and assuming the use of sophisticated communications technology a minimum spectrum bandwidth of 6.125 MHz is needed to satisfy reasonably anticipated requirements of most health care facilities today.[24] With reasonably anticipated growth, the Task Force believes that a minimum allocation of 6 MHz of bandwidth must be made available for immediate use today, with an additional allocation of 6 MHz to be made available for use over the next ten years, in order to assure biomedical telemetry operations in an interference-free environment. An allocation of *at least* 12 MHz of interference-free spectrum, available on a primary basis throughout the country, is essential to assure that the nation's needs for safe and reliable wireless biomedical telemetry capabilities will be satisfied.

III. Dedicated, interference-free bands must be identified to accommodate a multiplicity of different applications for wireless medical telemetry well into the next century.

Having identified the anticipated amount of spectrum which would be reasonably necessary to satisfy the needs for wireless biomedical telemetry, the Task Force's next major objective was to identify one or more spectrum bands in which such devices could operate in a relatively interference-free environment. In considering such bands, the Task Force was also sensitive to the need to accommodate a variety of potential applications -- some known, some not yet even considered -- for this technology in the burgeoning health care industry. The Task Force recognized that until new spectrum is identified and allocated, telemetry equipment manufacturers cannot feasibly begin the development of new products which will allow for the migration of users to the new bands.[25]

As a predicate to selecting suitable spectrum, the Task Force focused on real-time communications between the patient, his/her instrumentation, and a centralized monitoring/ processing site. In order to provide focus to its efforts, a workgroup developed a specific definition of wireless medical telemetry as "the measurement and recording of physiological

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[24] It must be noted, however, that this requirement was calculated based on a spectral efficiency of 0.8 bits per second per Hertz (the FCC's current recommendation), which is better utilization than medical telemetry technology currently affords. The Task Force also recognized that even this bandwidth might not satisfy the requirements of the largest facilities, and that it certainly would not satisfy any reasonable estimation of future requirements.

[25] As discussed in Section V below, the Task Force estimates that telemetry equipment manufacturers will require at least a 3-year period to bring products operating in these new bands to market, which is consistent with the likely budgeting cycles that will be faced by most health care facilities hoping to introduce the newer devices.

parameters and other patient-related information via radiated bi or unidirectional electromagnetic signals." Other communications devices (*e.g.*, pagers, *etc.*) used within a health care facility not directly meeting the Task Force's definitional parameters for wireless medical telemetry were not considered as part of this spectrum selection process.

The Task Force obtained input from liaison organizations including the FCC, FDA, NTIA and NAB; from informal discussions with members of wireless local area network and radio astronomy communities interested in the selection of frequency bands; and from a wide variety of interests in the medical telemetry field. The proposed bands for primary medical telemetry operations were chosen with several basic criteria in mind:

- Communications Reliability — medical telemetry monitoring is performed 24 hours per day; it was therefore essential to find bands in which co-channel and adjacent channel interference to medical telemetry operations would not generally exist.

- Spectrum Attributes — the selected spectrum had to have sufficient bandwidth, and it had to be suitable in supporting multiple modulation and transmission schemes for spectral efficiency and frequency re-use. Other spectral factors associated with a particular band were also considered (*e.g.*, path loss, level of noise floor, and susceptibility to multi-path fading). Finally, given the international marketplace for telemetering devices, consideration was given to whether the allocated use of the spectrum internationally was compatible.

- Operating Characteristics — the Task Force sought to minimize the recurring costs of ownership (*e.g.*, battery costs) and initial installation, equipment, and upgrade costs, including the ability to economically migrate any current users.

- Product Implementation Considerations — the current and anticipated availability of commercial RF components and low-cost field support instrumentation was considered, in order to provide some assurance that manufacturers and field technicians would be incented to bring new products to market in a timely fashion, and to facilitate the site survey/installation process; given the need to find spectrum to replace any channels that may be affected once they are utilized by higher powered land mobile transmitters after the "Refarming Order" applications freeze is lifted, it is essential that the bands chosen for the dedicated spectrum be among those in which cost-effective and expeditious manufacturing of product is clearly possible.

- Safety Considerations — the Task Force considered the susceptibility to RF radiated power to which other sensitive medical instrumentation would be exposed at particular frequency bands; the spectrum selected had to be efficient at field strengths not exceeding 3 V/m.

The Task Force was also concerned with finding channels in which the biomedical effects of radiofrequency exposure would not be problematic. In this regard, biomedical telemetry technology is carefully regulated by the Food and Drug Administration to assure that patient safety is not compromised in obtaining telemetry information. Nevertheless, in determining acceptable frequencies for dedication to wireless medical telemetry, the Task Force was cognizant of the amount of radiated power that the patient, as well as other sensitive medical instrumentation, would likely be exposed to in particular frequency ranges. In general, the higher operating frequencies would suffer additional path loss, mandating more radiated power to overcome, thereby introducing concerns for patient and device exposure. To reconcile these concerns, the Task Force reviewed ANSI/IEEE C95.1-1992 and assured that in each proposed spectrum solution, the energy that a transmitter would need to radiate to work effectively would be lower than the maximum permissible partial body exposure allowed for an uncontrolled environment.

Taking all of the above factors into consideration, the Task Force recommends the allocation of three distinct bands: 608-614 MHz ; 1385-1390 MHz ; and 1432-1435 MHz bands; for a total allocation of 14 MHz .[26]

In deciding to recommend the allocation of these bands, the Task Force found the following:

1. 608-614 MHz :

   - the band is currently authorized for medical telemetry use under Part 15, and thus multiple component vendors are available with off-the-shelf parts; it provides a strong opportunity for early development of newer devices, with a clear opportunity for quick migration of devices in particularly problematic interference situations.

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[26] The 1385-1390 and 1432-1435 MHz bands were recently identified by NTIA for reallocation to non-government use, in accordance with Title III, Section 3002(e) of the Balance Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251 (1997). *See* Spectrum Allocation Report, U.S. Department of Commerce, NTIA Special Publication 98-36 (Feb. 1998) (the "1998 NTIA Report").

- medical telemetry operations can be compatible with radio astronomy,[27] which is the predominant use of the band on a primary basis today; this will require frequency management for devices operating around such facilities.

- spectrum surveys revealed favorably low noise floors.

- although estimated path losses are higher than losses in the 470 MHz band, the differences are tolerable.

2. 1385-1390 and 1432-1435 MHz :

- there are already multiple component vendors available with off-the-shelf parts, facilitating the early introduction of devices operating in these bands.

- although the bands are currently in use by the federal government for radar operations, most of these operations must cease after 2008; thereafter, the use of the 1432-1435 MHz spectrum must be managed in expressly identified geographic exclusion zones affecting no more than 14 states; these bands would provide a strong area for future growth of the technology, as federal users migrate out of the band.

- estimated path loss is higher than at 470 MHz .

- spectrum surveys revealed low noise floors.

While not all of the characteristics of any of these bands are favorable, the Task Force believes that these bands hold the greatest promise for establishing an interference-free environment in which biomedical telemetering devices can operate effectively, efficiently and safely, on a primary or co-primary basis, with the least amount of disruption to other existing licensed services.

In this regard, perhaps the most difficult issues involve the use of these allocations in areas where these bands are currently authorized for use by radio astronomy service licensees (the 608-614 MHz band), and/or government radars (the 1385-1390 MHz band). Medical telemetry operations are currently authorized to operate in the 608-614 MHz band on a secondary basis; as the Commission noted in the 1997 R&O, "with regard to operation on TV channel 37, the Commission recognizes that most radio astronomy operations generally are

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[27] The Commission has already reached this conclusion in authorizing the operation of wireless medical telemetry devices operating in this band under Part 15. *See, e.g.*, 1997 R & O at ¶31.

located in rural areas where demand for biomedical telemetry devices is least. . . .[T]here may also be circumstances where there is a need for biomedical telemetry devices to be operated on TV channel 37 near such observatories [and] [t]his is a matter that must be addressed on a case-by-case basis."[28] As discussed below, the Task Force assumes that use near radio astronomy observatories would be managed by the designated frequency coordinator, in order to assure reasonable co-existence of these co-primary users. Similarly, as NTIA noted in the 1998 NTIA Report, the 1385-1390 MHz band is used primarily by military radar facilities, and will continue to be so used at several sites through the year 2008. The band 1432-1435 MHz is also used by the military for tactical radio relay communications, and essential federal government operations will have to be protected at certain designated sites indefinitely. The Task Force concluded that even as a co-primary user, medical telemetry devices would be able to coordinate with such federal government licensees sharing the band on a primary basis (at least through 2008), in those rare instances when medical facilities are sufficiently proximate to the other primary licensee as to have the potential for creating (or suffering) harmful interference. The Task Force concluded that, even with these limited geographical restrictions on the use of medical telemetry operations in these bands, interference to or from others can be avoided, and the bands can provide substantial value for wireless medical telemetering uses.

As to the licensing of spectrum allocated for wireless medical telemetry uses, the Task Force believes that the Commission can and should include this allocation within the definition of "public safety radio services" under Section 309(j)(2) of the Communications Act, as amended by the Balanced Budget Act of 1997,[29] thereby exempting it from auction.

The Balanced Budget Act of 1997 revised the Commission's auction authority by amending Section 309(j)(1) of the Communications Act so to require the Commission to award mutually exclusive applications for initial licenses or permits using competitive bidding procedures, except as provided in Section 309(j)(2). Sections 309(j)(1) and (2) now state:

> (1) General Authority. — If, consistent with the obligations described in paragraph (6)(E), mutually exclusive applications are accepted for any initial license or construction permit, then, except as provided in paragraph (2), the Commission shall grant the license or permit to a qualified applicant through a system of competitive bidding that meets the requirements of this subsection.
>
> (2) Exemptions. — The competitive bidding authority granted by this subsection shall not apply to licenses or construction permits issued by the Commission —

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28 1997 R&O at 17840.

29 P.L. 105-33, § 3002, 111 Stat. 251 (1997).

> (A) for public safety radio services, including private internal radio services used by State and local governments and non-government entities and including emergency road services provided by not-for-profit organizations, that--
>
> (i) are used to protect the safety of life, health, or property; and
>
> (ii) are not made commercially available to the public;
>
> (B) for initial licenses or construction permits for digital television service given to existing terrestrial broadcast licensees to replace their analog television service licenses; or
>
> (C) for stations described in section 397(6) of this title [applicable to "noncommercial educational" and "public" broadcast stations].[30]

There can be little doubt that health care facilities operating wireless medical telemetry devices are entitled to the exemption from competitive bidding applicable to "public safety radio services" under Section 309(j)(2)(A).[31] Medical telemetry devices are used by hospitals solely to save lives and preserve the health of patients, and they are not made commercially available to the public. The Commission recognized this fact recently when it stated that "it appears that frequencies used by medical telemetry equipment may fall within [the Section 309(j)(2)] exemption."[32]

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30 47 U.S.C. § 309(j)(1), (2) (as amended by Balanced Budget Act, § 3002).

31 It is significant to note that Congress made clear that the Section 309(j)(2) exemption for "public safety radio services" is "much broader than the explicit definition for 'public safety services'" included in Section 337(f)(1) of the Communications Act. *See* H.R. Conf. Rep. No. 105-217, 105th Cong., 1st Sess., at 572 (1997). For purposes of comparison, Section 337(f)(1) defines "public safety services" as follows:

> The term "public safety services" means services —
>
> (A) the sole or principal purpose of which is to protect the safety of life, health, or property;
>
> (B) that are provided (i) by State or local government entities or (ii) by nongovernmental organizations that are authorized by a governmental entity whose primary mission is the provision of such services; and
>
> (C) that are not made commercially available to the public by the provider.

47 U.S.C. § 337(f)(1).

32 *Implementation of Sections 309(j) and 337 of the Communications Act*, WT Docket No. 99-87, *Notice of Proposed Rule Making*, FCC 99-52 at ¶ 30 (released March 25, 1999).

The Task Force recognizes that the 1385-1390 MHz and 1432-1435 MHz bands were recently identified by NTIA for reallocation to non-Government use, in accordance with Title III, Section 3002(e) of the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251 (1997).[33] However, though this legislation requires that a certain amount of spectrum be reallocated, it does not mandate that competitive bidding be used to assign licenses to use the reallocated frequencies. Thus, the Commission has the authority to determine that these bands should be used for "public safety radio services" and therefore are exempt from competitive bidding under Section 309(j)(2).

Congress clearly did not intend that all spectrum reallocated pursuant to the Balanced Budget Act of 1997 would be auctioned.[34] Inclusion in this legislation of the public safety radio services exemption now found in Section 309(j)(2) indicates that reallocated spectrum need not be subjected to competitive bidding. Allocation of the 608-614 MHz, 1385-1390 MHz and 1432-1435 MHz bands for wireless medical telemetry uses thus would be consistent with the statutory scheme.[35]

IV. Maximum technical flexibility should be afforded within the allocated bands to encourage innovation, while also ensuring the maximum potential use of the band without creating co-band or out-of-band interference to other primary users.

As the Commission has consistently recognized in analogous circumstances, the least intrusive technical regulations are often the best technical regulations, and the Task Force has determined that this approach should hold true for any new spectrum allocation into which wireless medical telemetry uses may migrate. To that end, and following the approaches recently adopted, for example, in allocating spectrum for the use of U-NII,[36] the Task Force recommends

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33 These provisions are codified at 47 U.S.C. § 923(a) and (b). *See* 1998 NTIA Report.

34 Indeed, Section 3004 of the Balanced Budget Act of 1997 mandates reallocation to public safety use of certain frequencies currently used in UHF channels 60-69. *See* 47 U.S.C. § 337.

35 If the Commission feels it necessary to consider the potential revenue impact of exempting the 14 MHz from competitive bidding, it is worth noting that allowing medical telemetry use of these frequencies will clear other UHF spectrum, thereby increasing its potential value when auctioned.

36 "We continue to believe that the best regulatory framework to facilitate the introduction of U-NII devices is one that provides the maximum technical flexibility in their design and operation by imposing only the minimum technical rules necessary to prevent

(continued...)

that technical restrictions imposed on the use of these new bands should be limited to the following: (1) specifying the maximum allowable effective radiated power ("ERP"), (2) imposing a limitation on out-of-band emissions, and (3) requiring that all devices operating within these new bands should be subject to a "declaration of conformity" equipment authorization program. Moreover, and in order to maximize the sharing of the bands by both wideband and narrowband technologies, the Task Force recommends a limited channelization of the 608-614 MHz band only when used by devices employing wideband technologies. In addition, and as further assurance that the use of the new spectrum will be maximized, all users of the new bands would be required to register prior to use with a designated frequency coordinator as to the physical location at which the device will be installed; the modulation scheme utilized by the device; the ERP at which the device will operate; and the frequency range in which the device will operate, in order that an accurate database of device locations can be maintained, from which any incidents of interference can be resolved.[37]

In the view of the Task Force, it is critical that the industry be able to develop new and innovative products without the yoke of inflexible technical standards. Indeed, the Task Force hopes to encourage manufacturers to utilize different modulation types or schemes and any desirable channelization scheme within each band, without imposing any particular modulation efficiency standard and without being subject to particular frequency stability standards. Moreover, the Task Force believes that all types of information flows should be permissible in these bands on both a unidirectional and bi-directional basis. Only with such flexibility will

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[36] (...continued)
harmful interference to primary operations and to provide for basic spectrum sharing among unlicensed devices. . . . We believe that adoption of minimum technical rules would not only permit unlicensed devices to operate successfully on a shared basis, but would also encourage maximum flexibility in the types and designs of unlicensed digital devices that could use this band. . . . These rules specify power limits (in terms of peak power and power spectral density), emission limits, radio frequency hazard requirements, and other basic technical rules appropriate for unlicensed Part 15 operations. Further, . . . we are not adopting a channeling plan, spectrum modulation efficiency requirement or a spectrum etiquette as we believe such technical standards are unnecessary at this time, could preclude certain technologies, and could unnecessarily delay implementation of U-NII devices." *Amendment of the Commission's Rules to Provide for Operation of Unlicensed NII Devices in the 5 GHz Frequency Range, Report and Order*, ET Docket No. 96-102, 12 FCC Rcd 1576, 1592 (1997) ("U-NII Order").

[37] A more detailed description of the unique role anticipated for the designated frequency coordinating committee for the Wireless Medical Telemetry Service is attached as Appendix IV.

clinical users be able to drive manufacturers to develop different applications for medical telemetry.

In light of the highly competitive nature of the manufacturing industry for wireless biomedical telemetering devices, the Task Force does not believe that the lack of standards will lead to inefficient uses of these bands. To the contrary, by allowing the industry to move forward without government imposed standards, Task Force members believe that a high degree of innovation will result. Such innovation will be critical to meeting health care providers' desire to use technology to reduce risk to patients through more applicable and efficient monitoring; to the containment of costs of health care delivery; and to improvements in the quality of patient care through better diagnostic and monitoring data. And as potential uses of these bands increase, competitive manufacturers will be encouraged to use even more efficient technologies to develop new capabilities such as bi-directional telecommand, as dictated by future medical trends. In the view of the Task Force, limitations on the amount of maximum permissible power and limitations on out-of-band emissions, accompanied by a viable equipment authorization and user registration program, will be effective to accomplish these goals.

The only exception to this overall flexibility that the Task Force has considered is a modest limitation on the use of wideband technologies. The Task Force is aware of the substantial efficiencies that wideband technologies, for example some of the spread spectrum techniques, may bring to the industry in assuring that these new bands can accommodate the large number of devices anticipated for the future. On the other hand, there was some concern that the use of a wideband technology in a particular geographic area on a particular band could effectively inhibit the ability of other health care facilities (or even different health care practitioners within the same health care facility) within that area to also utilize narrowband techniques. To mitigate this concern, the Task Force recommends that the regulations provide that in the 608-614 MHz band, wireless medical telemetry devices utilizing broadband technologies such as spread spectrum shall be capable of operating within one or more channels of 1.5 MHz each,[38] up to a maximum of 6 MHz, and shall operate on the minimum number of such channels necessary to avoid harmful interference to any other wireless medical telemetry devices. Any wireless medical telemetry device operating in this band that utilizes wide band technology system should have the capability of being "throttled back" so that it will occupy as little as one of these 1.5 MHz channels, to the extent that narrowband systems operating in the area need to operate in one or more of the other channels to avoid interfering with, or being subject to interference from, such a wideband device. No similar restrictions are necessary in the other two allocated bands.

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[38] Specifically, this band would be divided for wideband systems, only, into the following four channels: 608-609.5 MHz, 609.5-611 MHz; 611-612.5 MHz; and 612.5-614 MHz.

In a similar circumstance, the Commission recently recognized that flexible technical regulations could be quite effective in allowing multiple users and multiple uses to co-exist without creating a substantial threat of interference to or among other users.[39] There is no reason to believe that the same considerations will not hold true for the burgeoning wireless medical telemetry industry, which should be able to coexist quite effectively with other remaining users of these reallocated bands without detailed technical restrictions or requirements.

Indeed, as an adjunct to the flexibility afforded under the technical rules, the Task Force strongly recommends that individual licenses would not be issued to users of devices operating in either the existing allocations or the newly allocated bands. Instead, the new service would be licensed "by rule," just as the Commission has done for the Family Radio Service (see, e.g., Section 95.401).[40] To maintain a reasonable basis for interference avoidance, however, any device operating in the new bands would require registration with a newly designated frequency coordinator prior to operation. Moreover, all such devices would continue to be subject to equipment authorization procedures under Part 2 of the rules, preferably to a manufacturers' "declaration of conformity" program.

While existing biomedical telemetry devices are operating primarily under the strictures of Parts 15 and 90, those sections may no longer be appropriate to allow for the regulatory parity which the Task Force believes is essential to the future growth and development of these critical health care capabilities in the newly allocated bands. To avoid any confusion in this regard, the Task Force recommends that a new rule part of the FCC's regulations should be created to accommodate use of the bands for biomedical telemetering. Suggested rules are included in Appendix III.

There are a number of alternatives for achieving this objective. First, the Commission could use the approach taken with Unlicensed PCS and U-NII devices, creating a separate section of Part 15, and requiring the database registration through a designated entity (much like UTAM is designated for certain spectrum management responsibilities under Part 15, Subpart D).

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39 As the Commission noted there, "we continue to believe that U-NII devices can share these bands with existing and future operations. . . .[T]he power limits, power spectral density requirements and emission limits that we are adopting herein will permit the robust development of U-NII devices without a significant impact on other spectrum users." U-NII Order at 1609.

40 Some accommodation must also be made in the FCC's rules to allow the operation of devices in this "licensed" service by health care facilities operated by federal government agencies, for example, the Veterans' Administration, so that the change from Part 15 regulation to a licensed service does not inadvertently impact such facilities ability to utilize wireless medical telemetry devices otherwise available to the rest of this sector.

Alternatively, and in the Task Force's view, the better approach, the new "Wireless Medical Telemetry Service" could be created under Part 90 or even under Part 95 -- or, if the Commission believes it to be appropriate, under a new Part 16 created for this and other "medical industry" devices -- allowing these devices to have the imprimatur of a "licensed" service.[41] In such case, however, the Commission should clearly license individual users and stations "by rule," much as it has done in creating the Family Radio Service.[42] Given the nature and number of devices that are anticipated to be operated in this new service, and the number of separate licensees that could co-exist in any given area, there is simply no basis for imposing the administrative burden of individual licensing. Moreover, these devices will be under the supervision and control of health care providers, who are, as a class, extremely sensitive to the need to avoid any radiofrequency interference. And the Task Force believes that the proposed device registration can be effective to anticipate and control inter-device interference. Medical telemetering devices and associated operations simply do not need to be licensed in order to provide regulatory parity with other licensed services.

A very important part of such "licensing" by rule is the ability of users, manufacturers and other licensees with whom this new service will, over time, continue to co-habitate in the spectrum, to access an accurate database of locations of low power devices operating in the new spectrum. The Task Force therefore recommends the appointment of a frequency coordinator who will maintain the requisite database, subject to the general restrictions imposed on designated frequency coordinators in accordance with the provisions of Section 332(b) of the Communications Act to provide database management services on a non-discriminatory basis for any user of a wireless biomedical telemetry device, maintaining a database of the following information:

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41 This approach (or a new rules section under Part 90) would have the additional advantage of allowing the Commission to designate all new radio services under the new Part 16 as "public safety services," thereby avoiding any doubt as to the ability of the Commission to issue licenses for these services without utilizing competitive bidding.

42 Amendment of Part 95 of the Commission's Rules to Establish a Very Short Distance Two-Way Voice Radio Service, FCC 98-293, WT Docket No. 95-102; RM-8499 (November 9, 1998). The Task Force is aware, however, of the need to expand eligibility for such a licensed service to recognize the rights of health care facilities operated by agencies of the Federal government to utilize devices operating in these new bands. Such health care facilities, *e.g.* hospitals operated by the Veteran's Administration, currently utilize biomedical telemetry devices operating under Part 15, and will therefore face the same problems as non-government facilities. The change to a licensed service should not prejudice these health care facilities' operations, so the rules adopted for the Wireless Medical Telemetry Service must accommodate their operations or allow for co-primary operations under the government allocation in these bands.

- legal name of end user
- location of transmitter (coordinates, street address, building)
- number of transmitters
- end user point of contact — name, office, position
- *frequency range(s) used (for wideband systems)
- *center frequency of operation (for narrowband systems)
- *modulation scheme used
- *effective radiated power
- *vendor legal name

As part of the manufacturer's declaration of conformity, each manufacturer would be required to provide each purchaser of a device with the items identified by an asterisk (*); moreover, and to further assure compliance with the registration requirements, the Commission should consider requiring each manufacturer of a wireless medical telemetry device operating in these new bands to provide with all new products sold to end user a standard registration form pre-printed with the asterisked information (thereby increasing the likelihood that the end user will have the requisite registration form and complete it for filing with the Coordinator).[43] Each user would be required to complete the registration form and submit it to the frequency coordinator, and further to re-submit a form at any time that the equipment is moved or changed, in order to assure that the database reflects current information. A registration would remain valid for a period of five years, at which time it could be renewed by a new registration if the device was still in use.[44]

A strong, centralized coordination system like that used in most of the other PLMR Services is not necessary for coordinating a Wireless Medical Telemetry Service. First, and foremost, health care providers will not expect or be granted any "protected service area" for the use of their devices, so it is less important to coordinate those licensees to obtain the desired protected area. Rather, the "license" associated with wireless medical telemetry devices will entitle the user to interference-free use of the devices, subject to the rights of other, similarly situated users of medical telemetry devices (and in some areas, other licensed services) to operate in the same general area, with similar protection. As with other low-powered services, it is anticipated that the technical regulations will provide the primary basis of protection for all users, without the need for frequency "coordination" oversight for each installation.

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[43] The Task Force believes that the modest expense associated with the printing of such forms will be more than offset by the substantial benefits that manufacturers will receive in assuring that an accurate database is available for planning the sale and installation of new products into a target health care facility/end user.

[44] The AHA is prepared to act as the initial frequency coordinator for these devices.

Second, the number and nature of licensees is quite different than in the PLMR Services, generally. Users of Wireless Medical Telemetry devices will be health care professionals, highly trained and dedicated to the patient care and safety; these licensed devices will not be used to advance their economic interests, per se, but rather as a key element of patient care. While there may be a multitude of user groups within a single health care environment, they will typically be under the management of the health care facility in which they are operating and, in light of the potentially devastating impact of interference, all users will be highly motivated to cooperate in advance of making any new installation, and also while operating any telemetry devices, to avoid being the creators of or being susceptible to such problems.

Third, and in the same vein, there is a relatively small manufacturing community for Wireless Medical Telemetry devices, and this community depends upon maintaining the satisfaction of those highly motivated health care practitioners in assuring that neither the technologies nor the designs of medical telemetry systems create internal or external interference to other similarly situated users. This community is also heavily regulated by the Food and Drug Administration in assuring that health and safety standards are maintained. Indeed, the competitive marketplace in which this manufacturing community is operating provides strong incentives for managing the use of the spectrum without the interposition of a central coordinating body.

In light of these factors the Task Force envisions a much less centralized functionality for the Wireless Medical Telemetry Coordinator; rather, the Coordinator's role will be as a database manager, centralized informational source and point of contact for anticipating the possibility of, and thus avoiding, potential interference among and between health care facilities and providers and any other authorized users of the allocated spectrum. The goal of this unique coordination system would be to accommodate all reasonable uses of the available spectrum in a variety of closely-spaced health care facilities, while avoiding unacceptable interference to neighboring health care providers and/or other licensed services.[45]

Nevertheless, to be effective, the registration process must have some potency. To that end, the Task Force envisions regulations under the Wireless Medical Telemetry Service that assure that the Coordinator is able to maintain an accurate engineering database of "licensed" wireless medical telemetry transmitters. Specifically, the rules must assure that no user of a

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[45] The Task Force also envisions that the Coordinator's database would be a helpful source of information in facilitating the transition of existing users to the newer frequencies, as the introduction of DTV and/or the use of higher powered devices by land mobile licensees in the offset channels in the 450-470 MHz band increases the potential for interference to grandfathered wireless medical telemetry devices operating under other sections of Parts 15 and 90.

medical telemetry device would be authorized to operate that device in this service unless, and until, it had filed a registration with the Coordinator.

With an accurate database assured by requiring registration in advance of installation, it would be the responsibility of each user (assisted by information supplied by the manufacturer from which the user is purchasing new products) to determine, in advance of installation, whether its new devices were likely to cause or be susceptible to interference from devices already registered in the Coordination database. The Task Force is convinced that health care practitioners will be highly motivated to use the registration system in order to avoid interference; the risks of doing otherwise are simply too great.

If, on review of the information in the database, interference was likely to occur from or to other registered devices, the proponent of the newly registered device would bear the responsibility of coordinating with existing users to avoid the interference. In the unlikely event that the users (with the assistance of their manufacturers) were unable to develop an engineering solution to the problem, then the Commission would be available to arbitrate such matters.

However, if interference occurred to any device that was not registered in advance with the Coordinator database, the operator of that device would have no protection from newly installed transmitters, and in fact would be required to resolve any interference problem at its own expense. The Task Force believes that this penalty will act as a significant deterrent to non-registration, as the failure to register would, in effect, lower the licensee's status to a "secondary" nature as to any subsequent installations within its area.

V. A reasonable transition is required to accommodate the manufacturing and budgeting cycles. All existing equipment should be grandfathered indefinitely.

As noted above, and in light of the increasing use of the existing bands by other, primary licensed services, it is critical to the health care industry that the FCC act quickly to identify and allocate new spectrum for wireless biomedical telemetering uses. Only when such bands have been allocated can manufacturers invest the capital and resources necessary to bring new and innovative uses of this technology to these new bands. Nevertheless, once the Commission has acted, time will be needed before the equipment capable of operating in these new bands is commercially available, and additional time will then be needed before health care facilities can budget the required funds to upgrade to these new devices.

The Task Force believes that a period of three years *after* the allocation of frequencies is completed will be needed before devices operating in these new bands are developed and being

competitively marketed.[46] Therefore, the Task Force has recommended that manufacturers should *not* be *required* to manufacture and market devices capable of operating in the newly allocated "primary" bands until at least four years after the adoption of an order allocating new spectrum for this service. In order to encourage development of products in these new bands, the Task Force therefore urges that all *newly designed* devices (*i.e.*, not those devices operating under Parts 15 or 90 that are merely being re-authorized to reflect minor modifications) that are first subject to an equipment authorization after the fourth year anniversary of a Report and Order allocating the new channels must be capable of operating in the newly allocated spectrum.

However, because health care facilities may desire to maintain the use of the existing Part 15 and Part 90 devices as long as they are not experiencing interference, manufacturers should be able to continue manufacturing and marketing devices operating in the existing allocations for as long as market demands warrant such activity.[47] **In addition, the use of any device lawfully manufactured and in operation should be grandfathered until it is replaced by the user.** The health care industry simply cannot afford to replace all of the myriad of existing wireless telemetry devices until they have outlived their usefulness, either because they are no longer in acceptable working order *or* because they are being operated in an area where they are subject to objectionable interference from other primary licensees.

In order to accommodate an orderly migration to the newly allocated spectrum, the health care industry will continue to need the use of the existing Part 15 and Part 90 spectrum allocations. To that end, therefore, the Commission must also maintain some part of the current Part 90 spectrum allocation available for low-powered uses. Lifting the licensing freeze across the *entire* 450-470 MHz band prior to a transition period of *at least* five years *starting with the*

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46 It must be remembered that all such devices will be subject to additional review and authorization by the Federal Food and Drug Administration as well as the Commission.

47 The Commission will need to distinguish between devices that are being redesigned and/or to which modest changes are being made (requiring, nevertheless, a new declaration of conformity) and those truly "new" product lines first introduced after the deadline. It is not the Task Force's intent to require all manufacturers to abandon their existing product lines, even after the new frequencies are allocated, until the marketplace demand for such products naturally creates such a result. To the contrary, there may continue to be some market for existing product to satisfy the demands of those hospitals in less urban areas where the spectrum congestion and/or introduction of DTV is not a problem, and where existing products will continue to satisfy patient health care requirements without creating any adversarial relationships with other primary licensees.

Report and Order allocating the new spectrum for Wireless Medical Telemetry, would create disastrous consequences to the wireless biomedical telemetry community.[48]

In any area where the freeze is lifted -- even rural areas where there is really no shortage of PLMR spectrum otherwise available to the land mobile community and where there are otherwise channels available today for medical telemetry -- health care facilities will have to assume that these channels will be assigned for high powered operations. Even in areas where there is no problem today, the situation could quite quickly deteriorate to become an area where there are few, or no, channels available in this band, since there simply will not be any way to readily regulate or identify any particular areas in which the unfrozen channels will be assigned,[49] particularly when mobile technology is involved, and even a lower powered mobile station has the ability to interfere with a truly low powered medical telemetry device. All health care facilities will accordingly have to plan to replace existing equipment with devices that will operate in the new band whenever the freeze is lifted from this 450-470 MHz band.

In this light, any transition must provide enough time (and potentially enough incentive) for the manufacturing community to develop and produce sufficient quantities of devices operating in the new bands to satisfy the potential demand that will develop once the freeze is lifted,[50] and for the medical community to purchase and install such devices. The transition must be sensitive to the design cycle needed by manufacturers once that new spectrum is allocated in order to bring devices to market on a wide scale basis; the transition must also account for the time element associated with the introduction by a typical health care facility of new biomedical telemetry devices which are replacing existing products to mitigate a potentially debilitating interference problem. Time is also needed to develop and react to the "registration" process that

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48 A determination by the Commission to lift the freeze from the 450-460 MHz band prior to the end of this five year transition may further exacerbate the shortage of channels in the upper 10 MHz portion of the band, as devices operating in the lower 10 MHz will be forced to migrate to the higher channels or to the newly allocated spectrum.

49 The Task Force has assumed that land mobile coordinators will not be able to develop and/or implement a method for coordinating high powered uses with lower powered telemetry systems.

50 Obviously the mere lifting of the freeze will not create an immediate flood of interference since land mobile users will need to obtain licenses and construct systems operating in these new channels. However, since there will be no way of knowing where the problems will exist in the near or mid-term environment, health care providers who have been relying on this band will have to be prepared to react (or assume the worst case scenario) to avoid being subject to devastating interference when the first licensees do begin operating on these offset channels in their areas.

will be introduced to assure that the new dedicated frequencies are most effectively utilized. Simply stated, a freeze must be retained to some degree for at least five years after new spectrum is allocated for wireless medical telemetry.

CONCLUSION

The Task Force is aware, and appreciative, of the efforts of the Commission's Office of Engineering and Technology and its Wireless Telecommunications Bureau, to develop solutions to the current potential for conflict between and among licensed uses of the VHF and UHF bands available for biomedical telemetering, and the low power biomedical telemetry devices which are currently operating in these bands. The efforts of the Task Force have been focused on assisting the Commission in those efforts. We believe that the attached workgroup reports, which in total represent the work product of the Task Force, can provide a strong basis on which the Commission can expeditiously issue a *Notice of Proposed Rule Making* and initiate the administrative processes necessary to create a "co-primary" allocation of spectrum for biomedical telemetering users. The Commission's urgent attention to this task is therefore requested.

APPENDIX I

TASK FORCE MEMBERS

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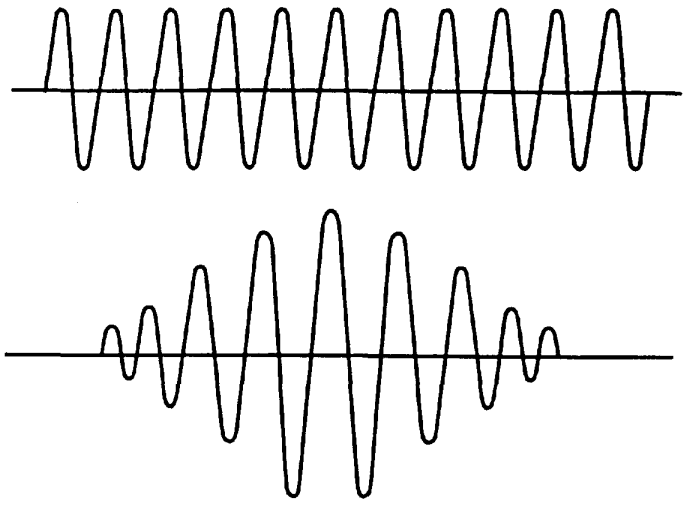
APPENDIX II

WORKGROUP REPORTS

FINAL REPORT OF THE WORKGROUP DEFINING WIRELESS MEDICAL TELEMETRY

December 17, 1998

YADIN DAVID, CHAIR



FINAL REPORT OF THE WORKGROUP DEFINING MEDICAL TELEMETRY

The working group recently completed its task of formulating a definition for present and future applications of medical telemetry systems. The process for arriving at the definition included a series of information exchanges between representatives from the user community, manufacturers of wireless medical telemetry equipment, members of the task force, the regulatory group, and information from professional societies. All input received was reviewed and considered before action was taken. Information received from other working groups, such as the data collected by the working group on parameters driving the spectrum allocation was considered as well. Via the internet, colleagues in other hospitals and professional organizations were able, in a fairly short time frame, to respond to various versions of the definition's draft presented to them. It is the intent of this working group to facilitate the safe, interference-free, and robust use of medical technology in general, and of medical telemetry in particular, at present and for the foreseeable future. This major effort should focus, as it does, on patient's needs and the capacity of medical telemetry to meet those needs.

Wireless Medical Telemetry is defined as follows:

Medical telemetry is defined as a measurement of something at a distance. Wireless medical telemetry is therefore defined as the measurement and recording of physiological parameters and other patient-related information via radiated bi or unidirectional electromagnetic signals. This technology may be contained within a healthcare facility or extend beyond to other buildings and locations.

FINAL REPORT TO THE AMERICAN HOSPITAL ASSOCIATION TASKFORCE ON MEDICAL TELEMETRY

December 17, 1998

PREPARED BY THE PHYSIOLOGIC PARAMETERS WORKGROUP

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FINAL REPORT TO THE AMERICAN HOSPITAL ASSOCIATION
TASKFORCE ON MEDICAL TELEMETRY
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EXECUTIVE SUMMARY

The Physiologic Parameters Workgroup was created to determine the spectrum bandwidth required to accommodate the needs of medical telemetry. These needs were determined through surveying fourteen hospitals of various sizes in both metropolitan and suburban/rural areas and various professional groups (Attachment A). Based on these survey results, the Workgroup determined what the spectrum needs would be today if appropriate patient care and communication technology were available to the medical community. The physiologic monitoring needs were defined as follows:

CURRENT TELEMETRY MONITORING NEEDS	
Physiologic Parameter	**Number of Concurrent Patients**
adult electrocardiogram	200 - 600
pulse oximetry	16 - 210
obstetrical (fetal/maternal) parameters	0 - 150
invasive pressures	17 - 420
respirations	4 - 210
12 sets of episodic data, e.g. noninvasive blood pressure, temperature.	up to 500 patients

The telemetry manufacturers represented in the Workgroup have determined that with the use of sophisticated communications technology, these physiologic parameters can be accommodated utilizing the following bandwidth:

Physiologic Parameter	**Concurrent Patient Use Model**	**Required Bandwidth**
electrocardiogram	500	4.000 MHz
pulse oximetry	250	0.150 MHz
obstetrical parameters	100	1.300 MHz
invasive pressures	300	0.400 MHz
respirations	100	0.025 MHz
12 sets of parametric data	500	0.250 MHz
TOTAL		6.125 MHz

These bandwidth calculations were based on a spectral efficiency of 0.8 bits per second per Hertz (the current FCC spectral efficiency recommendation).

This bandwidth will accommodate only today's patient care needs. There are several factors which will result in significant growth in spectrum needs over the next ten years. The main factor influencing this growth is that the patient acuity is rising, e.g. patients entering the hospital are sicker. This means that